

REMARKS

Claims 1-10, 15 and 17-22 are pending in the present application. The Office Action and cited references have been considered. Favorable reconsideration is respectfully requested.

Claims 1-6, 8-10 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (U.S. Patent No. 4,349,498) in view of McCrory et al. (U.S. Patent No. 6,333,971). Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis in view of McCrory and further in view of Hattori (U.S. Patent No. 5,989,258). Claims 15 and 17-20 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Sala Meseguer (U.S. Patent No. 6,093,023). These rejections are respectfully traversed for the following reasons.

Claim 1 recites a method to determine the position of a dental implant (2) which is fixed in the bone of the jaw (13) of a person, comprising the steps of fixing at least one marker element (3) which produces a strong contrast in imaging techniques to a free end (1) of the implant (2) in a detachable manner whereby the marker element (3) is situated at a distance (d) from the free end (1), generating an image of the jaw or of a reproduction model of the jaw by means of X-rays or magnetic resonance, wherein the jaw contains the implant (2) with the marker element, determining the position of the marker element (3) in relation to the jaw on the basis of the image which is formed by the X-rays or by the magnetic resonance, and identifying the position of the implant (2) from the observed position of the marker element (3). This is not taught, disclosed or made obvious by the prior art of record.

The Examiner asserts that Ellis et al. has a number of features in common with the method of claims 1-6, 8-10 and 21. Applicant respectfully disagrees.

First of all, claim 1 recites the step of *“fixing at least one marker element ... to a free end of said implant in a detachable manner whereby the marker element is situated at a distance from the free end”*.

Ellis discloses a method for producing a prosthetic member with a radiographic marker **fully encased** therein. The Examiner's attention is invited to the whole specification of Ellis and, for example, to column 1, lines 59-68. This paragraph explicitly mentions that *“... so that the foreign body is fully encased in the member and so that the member has an uninterrupted pyrolytic carbon surface....”*

It is clear that in Ellis, a marker is not fixed to an implant, but completely embedded in the implant during the manufacturing of the implant. It is thus not correct to state that in Ellis, a marker is fixed to an implant. Indeed, fixing a marker to an implant implies that the implant already exists in the form of a finished product and that the marker is attached to this product. Accordingly, Ellis does not teach fixing the marker to a free end of the implant, *i.e.*, to the exterior of the implant, in a detachable manner, as required in claim 1.

Thus, when claim 1 states that the marker is fixed to a free end of the implant, this would not have been understood by one of ordinary skill as a marker being fully encased in the implant.

Further, it is not possible to fix a marker to an implant, which is by definition a finished product, at a distance from the free end thereof such that the

marker is fully encased in the implant. Accordingly, Ellis does not disclose the method step of *"fixing at least one marker element which produces a strong contrast in imaging techniques to a free end of said implant in a detachable manner whereby the marker element is situated at a distance from the free end"*.

Additionally, it is important that claim 1 specifies that the marker is fixed to the free end of an implant that is fixed in the bone of the jaw. A dental implant that is fixed in the bone of the jaw only has one free end. This free end is the end of the implant that is extending out of the bone and that is sunk in the gums of the jaw.

The Examiner refers only to column 7, lines 44-51, to support the allegations concerning the claimed limitations being taught by Ellis. That portion of Ellis describes a dental implant wherein a radio opaque marker is fully encased in a root portion so that the position of the root portion may be monitored during and after implantation. This means that the marker of Ellis is encased in the portion of the implant that is situated near its end that is fully embedded in the jawbone and thus not the end that is sunk in the gums of the jaw.

However, such a marker encased in a root portion of the implant only allows detection of the presence of the implant and to verify whether during implantation a sufficient distance is maintained between the root portion of the implant and the mandibular nerve. It is indeed to be avoided that the implant pierces into the mandibular nerve during implantation. For this reason the wording "monitoring" is used by Ellis.

In contrast, the aim of the method of claim 1 is to determine the position of any dental implant that is fixed in the bone of the jaw. Such an implant does generally not have a marker that is encased in the implant. Ellis does not disclose determining the position of such an implant lacking an encased marker.

As stated correctly by the Examiner, Ellis does not teach attaching the marker element to the implant in a detachable manner. The Examiner cites McCroy for such a teaching, and asserts that the subject matter of the concerned claims is obvious through the combined teachings of Ellis and McCroy. Applicant respectfully disagrees.

McCroy discloses a fiducial marker system with markers that are removably attached to a corresponding base that is rigidly affixed to bone. In McCroy, the position of the base that is affixed to the bone, is of absolutely of no relevance. McCroy is only observing the position of the markers themselves and does not determine the position of the corresponding base. Further, the point of the invention of McCroy is to be able to introduce an imaging agent for improving imaging to allow obtaining high fidelity views of the body during diagnosis. McCroy does not teach and does not suggest attaching a marker element to a dental implant that is fixed in the jawbone.

Ellis discloses a method for producing a prosthetic member having a foreign body, such as a radio opaque marker, that is fully encased in the prosthetic member. Moreover, Ellis states explicitly that *"It is an object of the present invention to provide methods of implanting a foreign body in a substantially integral pyrolytic carbon prosthetic member so that the foreign body is fully encased in the member and so*

that the member has an uninterrupted pyrolytic carbon surface. More specifically, *it is an object of the invention to provide a method of forming a prosthetic member of pyrolytic carbon with a radiographic marker fully encased therein.*" (column 1, lines 60-68).

One skilled in the art would not combine Ellis and McCroy since there is no reason to combine the teaching of these documents. Since Ellis already has a radio opaque marker element, it makes no sense for one skilled in the art would to attach a supplementary detachably marker element of McCroy to the implant of Ellis. Additionally, the aim of Ellis is, as noted above, to have a marker element that is fully encased in the implant such that the implant has an uninterrupted pyrolytic carbon surface such that Ellis teaches away from an implant having a detachable marker. Further, to modify Ellis to use a detachable marker element, *i.e.*, to make the marker element not part of the implant itself, would render Ellis unsuitable for its intended purpose – to "provide methods of implanting a foreign body in a substantially integral pyrolytic carbon prosthetic member so that the **foreign body is fully encased in the member and so that the member has an uninterrupted pyrolytic carbon surface.**" *Id.*

For at least these reasons, Applicant respectfully submits that claim 1 is patentable over the prior art of record. Claims 2-6, 8-10 and 21 are believed to be patentable in and of themselves and for the reasons discussed above with respect to claim 1.

Further, with respect to claims 5-6, none of the cited documents teaches determining the orientation and position of the central axis of the implant by defining the centre of gravity of pixels representing the implant, as well as the centre of gravity of the image of the marker element.

It is well known to one skilled in the art that an X-ray image that is generated of metal part, such as a dental implant, which is enclosed by bone will provide only a blurry representation. The merit of Applicant's invention is that a very accurate determination of the position and orientation of this implant can be made on basis of such a blurry representation.

Determining a very accurate position for the implants is very important for producing a corresponding dental prosthesis that is to be fixed to the implant. Determining an accurate position of an implant on the basis of a blurry image never has been achieved according to the known state of the art. Simply stating that this would have been obvious for one having ordinary skill in the art is solely based on the use of impermissible hindsight reference to Applicant's disclosure.

With respect to claim 7, the Examiner alleges that this claim would have been obvious over Ellis et al. in view of McCrory and Hattori. Applicant respectfully disagrees.

Hattori does disclose a surgical stent (35) having multiple markers (57). However, the stent and the markers are not fixed to the implant and are only used for determining the positions and directions of drilling operation (see column 7, lines 11-38) before introduction of the implant into the jawbone.

In Hattori, the surgical stent with said multiple markers is removed before the implants are introduced in the jawbone such that the markers of the stent do not allow to determine the angular position of the implants in relation to their central axis. Thus it is not possible with Hattori to determine the angular position of an implant after it has been introduced into the jawbone.

Claims 15 and 17-20 were rejected as being unpatentable over Sala Meseguer. Claim 15 recites a support with a marker element (3,6) for determining the position of a dental implant (2) which is fixed to the jaw (13) of a person, in relation to this jaw (13), wherein the marker element (3,6) produces a strong contrast in an image generated by X-rays or magnetic resonance compared to said implant (2) itself. The support (4) has means at one far end to be fixed to said implant (2) in a detachable manner, whereas the other far end of the support (4) comprises the marker element (3,6). The means for fixing the support to the implant (2) comprise a securing pin (11), and the support comprises a sleeve (5) with a protrusion (15) whose dimensions correspond practically to those of a recess (8) provided in a head (1) of the implant (2) on which this support must be fixed, such that the protrusion (15) can be placed in a practically fitting manner in the recess (8). The sleeve (5) presents a second marker element (6). This is not taught, disclosed or rendered obvious by the cited prior art.

Sala does not teach the presence of a marker element and, as correctly stated by the Examiner, does not teach that the marker element produces a strong contrast compared to the implant itself in an image generated by X-ray or magnetic resonance.

According to the Examiner, the marker element of Sala is formed by upper tightening end (36) of a screw (35). However, it is not established that this tightening end of the screw is a marker element, and moreover, the material from which it is made is not disclosed by Sala.

Probably, the screw would be understood to be made of metal. However, in such case the tightening end of the screw would not be suitable to be used as a marker and does not produce a strong contrast compared to the implant itself in an image generated by X-ray or magnetic resonance. McCrory, for example, explicitly mentions that the solid metal is eschewed throughout for use as a marker. As already mentioned, a metal element produces a blurry image.

If the screw were to be made of plastic, it is certainly not suitable to be used as a marker element since it would, for example, be transparent for X-rays.

Moreover, Sala does not teach or suggest to make an image of its device generated by X-ray or magnetic resonance, or to use upper tightening end (36) of screw (35) as a marker element.

Consequently, stating that it would have been obvious for one skilled in the art to make the upper tightening end (36) of screw (35) of a material that produces a strong contrast in said image is solely based on impermissible hindsight.

For at least these reasons, Applicant respectfully submits that claims 15 is patentable over the prior art of record. Claims 17-20 are believed to be patentable in and of themselves and for the reasons discussed above with respect to claim 15.

New claim 22 has been added. Support for the limitations are found at least in paragraph [0036] of the original application as published under US2007/0141531. Applicant respectfully submits that none of the cited prior art teaches or suggests determining the position of the dental implant in relation to the jaw by calculating an exact position of the implant on a longitudinal axis of the implant on the basis of a previously determined distance between the marker element and the free end of the implant, as recited in claim 22. For at least this reason, and for the reasons discussed above with respect to claim 15, Applicant believes that claim 22 is patentable over the prior art of record.

In view of the above amendment and remarks, Applicant respectfully requests reconsideration withdrawal of the outstanding rejections of record. Applicant submits that the application is in condition for allowance and early notice to the effect is most earnestly solicited.

If the Examiner has any questions, he is invited to contact the undersigned at 202-628-5197.

Respectfully submitted,

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